SERIOUS, POSSIBLY ASSOCIATED AND UNEXPECTED ADVERSE EVENTS
REPORTED FOR HUMAN GENE TRANSFER PROTOCOLS
REPORTING PERIOD: 01/28/04 -- 04/27/04
RECOMBINANT DNA ADVISORY COMMITTEE MEETING
June 2004

Event #	OBA Date	Event Date	Protocol #	Event Description
			0101-452	**A Multicenter, Randomized, Double-Blind, Placebo Controlled, Dose-Response Study to Evaluate the Efficacy and Safety of Ad5.1FGF-4 in Patients with Stable Angina. Sponsor: Berlex Laboratories.**
6101	03/25/2004	03/19/2004		Subject with a long history of cardiac disease was found unresponsive after apparently suffering an unwitnessed cardiac arrest. Resuscitation efforts were unsuccessful. Death was deemed "possibly" related to the study agent, but further details of the circumstances were requested by the Principle Investigator.
			0101-456	**Phase I Study of a Recombinant Fowlpox Vaccine rF-CEA(6D)/TRICOM alone or with GM-CSF in Patients with Advanced CEA Expressing Adenocarcinoma.**
6035	02/18/2004	02/16/2004		Subject admitted for bleeding from colostomy. No other details known at this time.
			0107-490	**A Pilot Phase I/II Study of Intranodal Delivery of a Plasmid DNA (Synchrovax SEM Vaccine) in Stage IV Melanoma Patients. Sponsor: Mannkind Corporation.**
6124	03/26/2004	10/18/2002		Subject had a deep venous thrombosis. No significant details were given other than the event was of a "possible" relationship to the study agent. Thus, the study agent was discontinued.
			0205-538	**A phase I-II trial using dendritic cells transduced with an adenoviral vector containing the p53 gene to immunize patients with extensive stage small cell lung cancer after standard chemotherapy.**
6139	04/22/2004	04/10/2004		Aggravated by a lengthy car trip, the subject experienced generalized pain and arthralgias post-injection. These were deemed "expected and related" following vaccination.

Event #	OBA Date	Event Date	Protocol #	Event Description
			0301-568	**A phase II multi-center, double-blind, placebo-controlled, trial of VLTS-589 in subjects with intermittent claudication secondary to peripheral arterial disease**
6102	03/25/2004	01/03/2004		
6018	02/13/2004	01/12/2004		Subject presented to the Emergency Room with labored breathing, hiccoughs, and a two week history of nausea, vomiting and diarrhea. The subject was admitted to the hospital and the work-up uncovered moderately differentiated adenocarcinoma of the colon, atypical lymphoid proliferation, not metastatic in seven pericolonic nodes, and classic Hodgkin's disease mixed cellularity type in left lobe of liver and pericolonic nodes.
6019	02/13/2004	01/12/2004		Follow-up to Event #6018. On Study Day 35 the subject was diagnosed with Stage III Hodgkin's disease. The Investigator assessed this case of classic Hodgkin’s disease as "possibly related," but the Sponsor believes the temporal relationship between study drug administration and diagnosis of Hodgkin’s is not incompatible with that assessment.
			0302-571	**A phase II randomized study of GM-CSF gene-modified autologous tumor vaccine (CG8123) with and without low-dose cyclophosphamide in advanced stage non-small cell lung cancer**
6182	04/02/2004	05/16/2003		After tumor resection surgery, the subject developed significant amounts of bloody drainage from their chest tube. Subject was taken back to the operating room and was found to have a large bleed at the tumor resection site. Subject suffered cardiopulmonary arrest and was unable to be resuscitated. Final assessment of event by the investigator and the study sponsor was that the post operative bleeding related to surgical tumor harvest procedure led to death.